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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3375-N]

Announcement of the Approval of the Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program (formerly known as the American Osteopathic Association/Healthcare Facilities Accreditation Program) as an Accreditation Organization under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the approval of the application of the Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program (AAHHS/HFAP) as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for all specialty and subspecialty areas under CLIA. We have determined that the AAHHS/HFAP meets or exceeds the applicable CLIA requirements. We are announcing the approval and granting the AAHHS/HFAP deeming authority for a period of 4 years.

DATES: The approval announced in this notice is effective from March 29, 2019 to March 29, 2023.

FOR FURTHER INFORMATION CONTACT:

Kathleen Todd, (410)786-3385.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement

Amendments of 1988 (CLIA) (Pub. L. 100-578), which amended section 353 of the Public Health Service Act. We implemented the accreditation provisions of CLIA in the final rule published in the July 31, 1992 **Federal Register** (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of the AAHHS/HFAP as an Accreditation Organization

In this notice, we approve and grant deeming authority to the Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program (AAHHS/HFAP) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for all specialty and subspecialty areas under CLIA. We have examined the initial AAHHS/HFAP application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that AAHHS/HFAP meets or exceeds the applicable CLIA requirements. We have also determined that AAHHS/HFAP will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R.

Therefore, we grant AAHHS/HFAP approval as an accreditation organization under subpart E of part 493, for the period stated in the "DATES" section of this notice for all specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by AAHHS/HFAP during the time period stated in the "DATES" section of

this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a state survey agency to determine its compliance with CLIA requirements. However, the accredited laboratory may be subject to validation and complaint inspection surveys performed by CMS, or its agent(s).

III. Evaluation of the AAHHS/HFAP Request for Approval as an Accreditation

Organization under CLIA

The following describes the process used to determine that AAHHS/HFAP accreditation program meets the necessary requirements for approval by CMS as an accreditation program with deeming authority under the CLIA program. AAHHS/HFAP formally applied to CMS for approval as an accreditation organization under CLIA for all specialties and subspecialties under CLIA. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations.

A. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption under an Approved State Laboratory Program

AAHHS/HFAP submitted information required under §493.553 including a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements, a detailed description of the inspection process, a statement concerning whether inspections are announced or unannounced, a description of the process for monitoring proficiency testing (PT) performance, a list of all its current laboratories and the expiration date of their accreditation, and procedures for making PT information available. The AAHHS/HFAP policies and procedures for oversight of laboratories performing laboratory testing for all CLIA specialties and subspecialties are equivalent to those of CLIA in the matters of inspection, monitoring proficiency testing (PT) performance, investigating

complaints, and making PT information available. AAHHS/HFAP submitted additional information as required in §493.557 including its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements within the scope of specialty and subspecialty areas for which it requested deeming authority, a description of its data management and analysis system with respect to its inspection and accreditation decisions, detailed information concerning the inspection process, procedures for removal or withdrawal of accreditation status, a proposed agreement with CMS with respect to the notification requirements, and information demonstrating its ability to provide CMS with required electronic data and reports, adequacy of staffing and other resources, and adequacy of funding for performing required inspections. The requirements of the accreditation program submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

B. Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

AAHHS/HFAP's requirements are equal to or more stringent than the CLIA requirements at §§493.801 through 493.865 for participation in PT for laboratories performing nonwaived testing. Like CLIA, all of AAHHS/HFAP's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in subpart I.

C. Subpart J—Facility Administration for Nonwaived Testing

The AAHHS/HFAP requirements for the submitted subspecialties and specialties are equal to the CLIA requirements at §§493.1100 through 493.1105 for facility administration for nonwaived testing.

D. Subpart K—Quality System for Nonwaived Testing

The AAHHS/HFAP requirements are equal to the CLIA requirements at §§493.1200 through 493.1299 for quality systems for nonwaived testing.

E. Subpart M—Personnel for Nonwaived Testing

We have determined that the AAHHS/HFAP's requirements are equal to the CLIA requirements at §§493.1403 through 493.1495 for personnel for nonwaived testing for laboratories that perform moderate and high complexity testing.

F. Subpart Q—Inspections

We have determined that the AAHHS/HFAP requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at §§493.1771 through 493.1780 for inspections. AAHHS/HFAP will continue to conduct biennial onsite inspections consistent with the requirements at §§493.1771 through 493.1780.

G. Subpart R—Enforcement Procedures

AAHHS/HFAP meets the enforcement procedures requirements of subpart R as applicable accreditation organizations. AAHHS/HFAP policies set forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, AAHHS/HFAP will deny, suspend, or revoke accreditation of a laboratory accredited by AAHHS/HFAP and report that action to CMS within 30 days. AAHHS/HFAP also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked. We have determined that AAHHS/HFAP's laboratory enforcement and appeal policies are equal to the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

Consistent with the requirements at §§493.563 through 493.571, the federal validation inspections of laboratories accredited by AAHHS/HFAP may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or

the state survey agencies, will be our principal means for verifying that the laboratories accredited by AAHHS/HFAP remain in compliance with CLIA requirements. This federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Section 493.575 provides that we may rescind the approval of an accreditation organization, for cause, before the end of the effective date of approval if we determine that the accreditation organization has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes. We may impose a probationary period, not to exceed 1 year, in which the accreditation organization would be allowed to address any identified issues. Should the accreditation organization be unable to address the identified issues within that timeframe, we may revoke accreditation organization's deeming authority under CLIA in accordance with applicable regulations.

Should circumstances result in our withdrawal of AAHHS/HFAP's approval, we will publish a notice in the **Federal Register** explaining the justification for removing its deeming authority.

VI. Collection of Information Requirements

This document does not impose information collection requirements that is reporting, recordkeeping or third party disclosure. Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. Chapter 35).

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Dated: March 15, 2019.

Seema Verma,
Administrator,
Centers for Medicare & Medicaid Services.

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